K063752

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

MAY - 4 2007

Submitter: Nonin Medical, Inc.

Contact Person:
Lori M. Roth
Clinical/Regulatory Specialist
Nonin Medical, Inc.
13700 1st Ave. North
Plymouth, MN 55441-5443

Date Prepared: December 15, 2006

Trade Name: LifeSense® Model LS1-9R Capnography/Pulse Oximeter Monitor

Classification Name: and Number: Class II, 21 CFR 868.1400

Product Code: DQA, CCK

Predicate Device(s): Nonin's LifeSense® Model LS1-9R is substantially equivalent to the MicroCap Plus/NPB-75 Capnograph/Pulse Oximeter manufactured by Oridion Medical, LTD cleared by the FDA under K024300 on 4/03/03 and the Capnocheck® Plus manufactured by BCI International, Inc. cleared under K970209 on 4/18/97.

Device Description: The LifeSense® Model LS1-9R is a lightweight, portable Capnography/Pulse Oximeter monitor indicated for use in simultaneously measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), end tidal carbon dioxide ($ETCO_2$), respiration and pulse rate of adult, pediatric, and infant patients. It is intended for use in any environment where patients require continuous, non-invasive monitoring of intubated or spontaneous breathing patients.

When measuring $ETCO_2$ the patient is attached to the monitor by a simple sample line that can be either an airway adapter for an endotracheal tube, a nasal cannula, or a nasal cannula with oxygen input.

The liquid crystal display (LCD) monitor of the Model LS1-9R displays factory default or operator defined

parameters and alarm settings, $ETCO_2$ and respiration graphs, battery status and fault messages. Operator defined settings can be made on the touch panel display.

LifeSense Model LS1-9R monitor is intended for prescription use with adult, pediatric, and infant patients.

Intended Use:

The LifeSense® Model LS1-9R Capnography/Pulse Oximeter monitor indicated for use in simultaneously measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), end tidal carbon dioxide ($ETCO_2$), respiration and pulse rate of well or poorly perfused adult, pediatric and infant patients. It is intended for use in environments where patients require continuous, non-invasive monitoring of these parameters by a healthcare professional, e.g. hospitals, medical facilities, post-operative care, patient transport, home-use, or any emergency medical services and environments.

Functional and Safety Testing:

Nonin's Model LS1-9R Capnography/Pulse Oximeter monitor has undergone both bench and clinical testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate devices.

Conclusion:

Nonin's LifeSense Model LS1-9R is substantially equivalent to the MicroCap Plus/NPB-75 Capnograph/Pulse Oximeter manufactured by Oridion Medical, LTD cleared by the FDA under K024300 and the Capnocheck® Plus manufactured by BCI International, Inc. under K970209.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lori M. Roth
Clinical/Regulatory Specialist
Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minnesota 55441-5443

MAY - 4 2007

Re: K063752
Trade/Device Name: Nonin LifeSense® Model LS1-9R Capnography/ Pulse Oximeter Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: April 25, 2007
Received: April 27, 2007

Dear Ms. Roth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

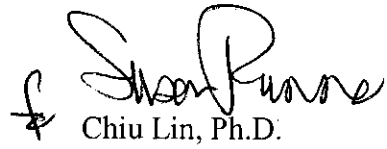
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K063752

Device Name:

Nonin LifeSense® Model LS1-9R Capnography/Pulse Oximeter Monitor

Indications for Use:

The LifeSense® Model LS1-9R Capnography/Pulse Oximeter monitor indicated for use in simultaneously measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), end tidal carbon dioxide ($ETC0_2$), respiration and pulse rate of well or poorly perfused adult, pediatric and infant patients. It is intended for use in environments where patients require continuous, non-invasive monitoring of these parameters by a healthcare professional, e.g. hospitals, medical facilities, post-operative care, patient transport, home-use, or any emergency medical services and environments.

Prescription Use ___X____	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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